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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,963	12/30/1999	ROGER L. BUIS	BO999023-003	7122

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EXAMINER	
LUDWIG, MATTHEW J	

ART UNIT	PAPER NUMBER
2178	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/475,963	BUIS ET AL.	
	Examiner	Art Unit	
	Matthew J. Ludwig	2178	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19,20 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19,20 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the Request for reconsideration filed 4/21/2006.

2. Claims 1-17, 19, 20, and 24 are pending in the case. Claims 1, 10, 17, and 24, are independent claims.

3. Claims 1-6, 10-17, 19, 20, 24, and 25, remain rejected under 35 U.S.C. 103(a) as being unpatentable over Umen et al., USPN 6,854,086 filed (11/13/02).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 1-17, 19, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umen et al., USPN 6,854,086 filed (11/13/02).**

In reference to independent claim 1, Umen teaches:

Section headings may be included in the document templates for identifying the various sections of each document. At each location within the document template where a data object is to be retrieved from the clinical study data base, there is a control code identifying which object is to be retrieved (compare to "***associating an identifier with each record in a data stream at a first computer, the identifier indicating a type of information included within a data record***"). See column 17, lines 20-35.

Each of the document templates specifies the type and order of data objects that are to be retrieved from the clinical study database in order to produce a standard drug document in accordance with FDA, EU, Company, or other predetermined document formats. Table 1 lists representative study details that may be specified within representative standard types of documents (compare to "***associating each identifier with a format region, each format region defining an area on a document page***"). See column 10, lines 35-55.

When the user selects Document Generation from the main menu, the DMUI provides a series of study selection menus which allow the user to specify whether the desired document pertains to a single study or whether the desired document integrates data from more than one study, and to select the study of interest (compare to "***specifying parameters for each format region, where the parameters include formatting instructions relating to the presentation of the data records in a document at a second computer***"). See column 17, lines 33-67. The reference fails to explicitly state the parameter are directly related to a format region; however, the parameters selected by the user for specifying dates of studies suggests the placement of data into specific regions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the parameters and predefined templates for the transmitting of document layouts effecting specific document regions for production of a standard drug document in accordance with FDA, EU, Company, or other predetermined document formats.

When the DMUI has completed generating the document, the document can be provided to the word processor for any desired editing or refinement by the user (compare to "***formatting each data record within the corresponding format region according to the parameters specified at the second computer***"). See column 19, lines 25-45.

In reference to dependent claim 2, Umen teaches:

In addition to specifying study details, text objects, and the arrangement thereof, the document templates may include standard plain text items that are usually included in the respective documents. See column 17, lines 20-27. The reference does not explicitly state formatting instructions are specified for each format region, however, based on the selection of the template by the user, specific regions of the document will be formatted based on a specific template. Therefore, it would have been obvious to one of ordinary skill in the art, having the teachings of Umen, to utilize the well-known methods of a template to format different regions of a document based on specific data because it would have given the reader an organized approach to analyze data produced by the data request.

In reference to dependent claim 3, Umen teaches:

When the user selects Document Generation from the main menu, the DMUI provides a series of study selection menus which allow the user to specify whether the desired document pertains to a single study or whether the desired document integrates data from more than one study. If a multiple-study document is selected, then the DMUI provides selection menus for selecting the multiple studies from which data is to be used in the document. See column 17, lines 33-43.

In reference to dependent claim 4, Umen teaches:

When the DMUI has completed generating the document, the document can be provided to the word processor for any desired editing or refinement by the user. Additionally, the user may then instruct the word processor to operate the printer for printing the generated document. See column 19, lines 35-45.

In reference to dependent claim 5, Umen teaches:

Section headings may be included in the document templates for identifying the various sections of each document. At each location within the document template where a data object is to be retrieved from the clinical study database, there is a control code identifying which object is to be retrieved. See column 17, lines 23-27.

In reference to dependent claim 6, Umen teaches:

The retrieved detail object is then placed into the document as detail text. When the detail text is inserted into the document, the DMUI also places a delimiter code, represented in FIG. 7. See column 18, lines 30-46.

In reference to dependent claim 7, Umen teaches:

Figure 2 illustrates a communications network which includes a printer, display, keyboard, word processor, data management user interface, which inherently provides a communications network.

In reference to dependent claim 8, Umen teaches:

The reference provides a communications network which is illustrated in figure 2. The reference fails to explicitly state a third computer used for performing similar methods as discussed in the rejection of the independent claim; however, the data management user interface could provide records to multiple user if they requested records from a third computer. It would have been obvious to one of ordinary skill in the art to modify the communications network disclosed in Umen to further provide different users requesting similar data to illustrate a network of computers assigned to one specific task.

In reference to dependent claim 9, Umen teaches:

If the referenced detail has not yet been entered into the detail files of the current study, then the DMUI will fail to retrieve the selected data. See column 8, lines 55-67. The reference fails to explicitly state the computer is unable gain access; however, if the referenced detail has not yet been entered is suggestive of the second computer unable to gain access to the data if the referenced detail has not been entered.

In reference to claims 10-12, 14-16, 17, and 24, the claims recite similar limitations to those found in 1 and 3-7 for carrying out the formatting methods. Therefore, the claims are rejected under similar rationale.

In reference to claims 13, 19, and 20, the claims recite similar limitations to those found in 2, 8 and 9 for carrying out the formatting methods. Therefore, the claims are rejected under similar rationale.

Response to Arguments

6. Applicant's arguments with respect to claims 1-17, 19, 20, and 24, have been considered but are not pursuasive.

More specifically, applicant argues on page 7 of the request for reconsideration that Umen does not disclose specifying parameters for each format region defining an area on a document page. Instead, applicant points to the fact that Umen discloses using templates to format a document (FDA report template) and such a template formats all the regions of a document according to the template. The Examiner reasons that based on the limitation of the independent claim, as presently stated, the template utilized by Umen, specifies parameters for

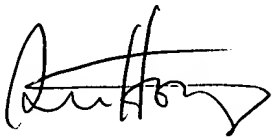
each format region, where the parameters include formatting instructions relating to the presentation of the data records. Because the claim limitations are to be given their broadest reasonable interpretation within the scope of the art, the Umen reference suggests a template to define formatting instructions for each format region in a document. When the user selects Document Generation from the main menu, the DMUI provides a series of study selection menus which allow the user to specify whether the desired document pertains to a single study or whether the desired document integrates data from more than one study, and to select the study of interest. See column 17, lines 33-67. The reference fails to explicitly state the parameter are directly related to a format region; however, the parameters selected by the user for specifying dates of studies suggests the placement of data into specific regions by the template. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the parameters and predefined templates for document layouts and effecting specific document regions for production of a standard drug document in accordance with FDA, EU, Company, or other predetermined document formats.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Ludwig whose telephone number is 571-272-4127. The examiner can normally be reached on 9:00am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Hong can be reached on 571-272-4124. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ML
July 7, 2006

STEPHEN HONG
SUPERVISORY PATENT EXAMINER